

ACTION REQUEST

Subject: Research Agreement between the University of Michigan and Food Allergy Research & Education, Inc.

Action Requested: Authorization to enter into Research Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects while reviewing the Proposal Approval Form which then triggered a review by the Medical School Conflict of Interest Board. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by the Board and agreed to by the parties involved.

This proposed agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professor James R. Baker, Jr. is an employee of the University of Michigan ("University"), and Chief Executive Officer and Chief Medical Officer of Food Allergy Research & Education, Inc. ("FARE"). The law permits such an Agreement provided it is disclosed to the Board of Regents ("Regents") of the University of Michigan and approved in advance by a 2/3 vote.

Background:

Dr. James R. Baker, Jr., a Professor of Internal Medicine, is the Chief Executive Officer and Chief Medical Officer of a non-profit organization called FARE (the "Company"). The Company wishes to fund a project entitled "Modulation of food allergy responses with nanoemulsion-based allergy vaccines" (ORSP# 15-PAF03099) in the MI Nanotechnology Institute under the direction of Dr. Jessica O'Konek. The purpose of this project is to investigate immunomodulation of Th2- and IgE-mediated allergic hypersensitivity with intranasal administration of NE combined with egg or peanut antigens and to characterize the protection induced by NE in challenge models of allergic hypersensitivity and anaphylaxis to food allergens.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately two (2) years. The amount of funding support will not exceed \$150,000. Since research projects are often amended, this agreement includes a provision for changes in time, amount, and scope. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

Impact of the Agreement

The Agreement will support an effort by Dr. O'Konek to use her expertise and University laboratory, as well as other University resources to develop a vaccine protocol that can be tailored to all patients with food allergies.

Recommendations:

This matter has been reviewed and approved by the Medical School Conflict of Interest Board. In light of this disclosure and our finding that the Agreement was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the University's entering into this Agreement with Food Allergy Research & Education, Inc.

Respectfully submitted,



S. Jack Hu
Interim Vice President for Research

June 2015